K072710

510(k) Summary as required by section 807.92(c)

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: September 24, 2007
Applicant: Nexa Orthopedics, Inc
a Tornier Company
11035 Roselle Street
San Diego, CA 92121
Telephone: 858-866-0660 x 155
Fax: 858-866-0661
Contact: Corey Wilson-Wirth

NOV 0 8 2007

Common Name:	Threaded pin
Device Trade Name:	NexFix™ Compression Pin
Device Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	888.3040
Product Code:	87 JDW
Predicate Device:	K051740, Tapered Compression Pin, Futura Biomedical K993910 TAC Pin, Newdeal
Registration Number:	2030833
Owner Operator Number:	9100540

Device Description:

The Nexa Orthopedics, Inc Implant is a one-piece device made of Stainless Steel or Titanium Alloy, intended for fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis. The implant is designed in 10 sizes. The device is tapered and threaded on the leading end and smooth on the trailing end. The implant is used in the treatment of bone fractures or bone reconstruction, including osteotomy, and joint fusion. The design of the NexFix™ Compression Pin is similar to the predicate devices. No new materials or processes are used in the development of this implant.

Indications for Use:

The NexFix™ Compression Pin is intended to be implanted for the fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis of the foot and ankle and hand and wrist.

Comparison to Predicate Device:

Similarities of the NexFix Compression Pin to its predicates include these devices being: intended for single use only, intended for surgical implantation longer than 30 days, system consisting of a series of pins or various diameters and thread lengths, made of industry standard materials, with no new materials being introduced in the product, comparably sized, and indicated for the same uses.

Summary:

The device and the predicate device have the same design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2007

Nexa Orthopedics, Inc.
a Tornier Company
% Mr. Corey Wilson-Wirth
11035 Roselle Street
San Diego, CA 92121

Re: K072710
Trade/Device Name: NexFix™ Compression Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: September 24, 2007
Received: September 25, 2007

Dear Mr. Wilson-Wirth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

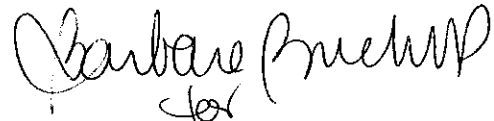
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072710
Device Name: NexFix™ Compression Pin
Indications for Use:

The NexFix™ Compression Pin is intended to be implanted for the fixation of bone fractures, bone reconstruction, osteotomy or arthrodesis of the foot and ankle and hand and wrist.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072710